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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,515	11/28/2001	Shuqian Jing	00-659-A	1848

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/995,515	Applicant(s) JING, SHUQIAN	
	Examiner Janet L. Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,10,43-45,50,56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 10, 43-45, 50, 56, and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 21 September 2004 is acknowledged. Claims 1, 4-8, 10, 43-45, 50, 56, and 57 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The rejection of claims 5 and 6 under 35 U.S.C. 101 as being drawn to non-statutory subject matter is withdrawn in response to Applicant's amendment requiring that the cells be isolated.

Claim Rejections Maintained

3. The rejection of claims 1, 4-8, 10, 11, 43-45, 50, 56, and 57 under 35 U.S.C. 101 because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility is maintained for reasons of record in the office actions of 26 June 2003 and 15 March 2004.

Applicant argues that the claimed inventions have similarity to GDF-3 and that the location of the cysteine residues is conserved between these two proteins. Applicant states that the claimed invention is related to a sub-family of the TGF- β family, the BMP family. Applicant states that BMP signaling is important during development and growth. Applicant asserts that the artisan would recognize that the invention has a credible utility in regulating cell growth and development in prostate, testis, ovary, and/or liver.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated on p. 4 of the office action of 26 June 2003 and p. 3 of the office action of 15 March 2004, no function has been identified for GDF-3. Therefore, homology to this protein

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does not endow the current invention with a utility. Further, that BMPs are generally involved in growth and differentiation does not provide any information as to how a particular member of this family is involved and thus as to how it could be used. Myazano et al., cited in the previous office actions, teaches that BMP-2 and BMP-4 induce bone and cartilage, GDF-8 inhibits muscle cell proliferation, and GDF-5 induces "cartilage-like structures" (p. 267, column 1). Thus the functions of members of this family differ. The credibility of Applicant's assertions is not challenged; however, the asserted utility of regulating cell growth and development in "prostate, testis, ovary, and/or liver" is not substantial. There is no information as to how growth and development are affected by the invention. There is merely the statement that it is somehow involved in these processes in one or more of the tissues in which it is found. Clearly, further research is required to ascertain what its function is and thus how it could be used.

4. The rejection of claims 1, 4-8, 10, 43-45, 50, 56, and 57 under 35 U.S.C. 112, first paragraph, as lacking enablement because the invention lacks utility is maintained for reasons of record in the office actions of 26 June 2003 and 15 March 2004.

Applicant argues that affirmative evidence has been set forth that the asserted utility is specific and substantial and would be credible to the artisan.

Applicant's arguments have been fully considered but have not been found to be persuasive for the reasons set forth in paragraph 3 above.

5. The rejection of claims 1, 4-8, 10, 43-45, 50, 56, and 57 under 35 U.S.C. 112, first paragraph, as lacking enablement for and written description of variants is maintained for reasons of record in the office actions of 26 June 2003 and 15 March 2004.

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Applicant argues that the claims do not have fragment language. Applicant argues that the only variants claimed must hybridize under specified stringent conditions. Applicant argues that it would require only routine experimentation to make and use such molecules. With respect to the written description rejection, Applicant again argues that the claims do not have fragment language. Applicant argues that the variants are described by their hybridization characteristics. Applicant cites *Enzo Biochem.* as holding that this limitation is sufficient.

Applicant's arguments have been fully considered but have not been found to be persuasive. It is agreed that the fragment language has been removed. However, as was stated in the previous rejection, the claims still encompass sequences that are not identical to the disclosed sequences and that need not have a common function. Thus, while the artisan might be able to generate a number of these molecules, they would have no particular function and thus it would require undue experimentation for the artisan to use them. That part of *Enzo* cited by Applicant is actually a reference to Example 9 of the PTO Written Description Guidelines. Example 9 describes a claim to molecules identified by hybridization which encode a protein that has a particular function. The court held that the question was one of fact:

On remand, the court should consider whether one of skill in the art would find the generically claimed sequences described on the basis of Enzo's disclosure of the hybridization function and an accessible structure, consistent with the PTO Guidelines. If so, the written description requirement would be met.

Thus there was no decision that the genus was necessarily described, only that, depending on the facts, it is possible that it was. Here, there is no requirement that the molecule encode a protein with a particular function, as in Example 9 of the PTO Guidelines. There are no other common defining features required. Thus Applicant has not described and is not in possession of a genus of polynucleotides.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
10 December 2004



JANET ANDRES
PRIMARY EXAMINER